K130269

# 510(k) summary

(in accordance to 21 C.F.R. § 807.92)

APR 19 2013

## Submitter Identification


| | |
|---|---|
| Holder / Headquarters: | MiE GmbH<br>Hauptstrasse 112<br>23845 Seth, Schleswig-Holstein<br>Germany |
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Date summary prepared: 8th January 2013

## Product Identification

| | |
|---|---|
| Name: | ECAT Scintron PET |
| Common Name: | Nuclear Medicine Workstation<br>for Acquisition, Viewing and Processing |
| Classification Name: | Emission computed tomography system<br>21 C.F.R. § 892.1200 |
| Classification: | Class II |

## Identification of Legally Market and Equivalent Devices

| 510(k) # | Device | Manufacturer |
|---|---|---|
| K962797 | ECAT EXACT PET System | CTI PET Systems, Inc. |
| K002584 | ECAT ACCEL PET Scanner | CTI PET Systems, Inc. |

## Device Description

The 'ECAT SCINTRON PET' is designed to replace the integrated workstation (advanced computational system) of the legally market devices ECAT EXACT PET System and ECAT ACCEL PET scanner.

The 'ECAT SCINTRON PET' integrated workstation is proposed to perform simultaneous 2D or 3D acquisitions, image reconstruction, processing and analysis of data received from ECAT Positron Emission Tomographs of CTI PET Systems. In addition it controls the motion of the patient handling system, the transmission sources and septa for 2D scans with the scanner.

The 'ECAT SCINTRON PET' is used to acquire data from whole body positron emission tomography system and providing 3D volume measurements of metabolic and physiologic processes.

The software is designed to run only on 'ECAT SCINTRON PET' integrated workstations. The software is only available as package and in combination with the computer hardware. Some software modules not needed for the basic usage are optional.

The development processes of the software and hardware are based on the legally market device, name SCINTRON, K101013. The 'ECAT SCINTRON PET' uses industry standard and well tried hardware components and software techniques which ensures long term support.

## Indications for Use

The 'ECAT Scintron PET' integrated workstation is designed to acquire data, process and display images, by appropriated trained health care professionals, from ECAT EXACT and ECAT ACCEL PET scanners of CTI PET Systems via measuring the distribution of injected positron emitting radiopharmaceutical in humans for purpose of determining various metabolic and physiologic functions within the human body.

## Performance

Generally the CTI PET scanner itself, including its specification regarding performance is not modified. The usage of the same coincidence board and gantry communication board (including patient handling system) is necessary.

As in the OEM integrated workstation, the computers are divided into an acquisition and an evaluation part. The acquisition is done by a powerful industrial VMEbus PowerPC with a real-time operating system OS9. This makes the acquisition safe and stable. For processing and viewing a state-of-the-art Windows PC with a multi core processor, at least 3 GByte RAM modules as well as state-of-the-art graphical interfaces and network components is used. Both computers, the PowerPC and the PC communicate via a TCP/IP interface, same as in the original integrated workstation (ACS<(TCP/IP)>SUN).

## Device Comparison

The integrated workstation 'ECAT SCINTRON PET' is similar to the integrated workstation of the PET Scanner, name ECAT EXACT PET System, K962797 and name ECAT ACCEL PET Scanner, K002584. This involves all computer applications as well hardware interfaces.

The major difference is the improvement of available electronics components as well as state-of-the-art software techniques for the acquisition, processing and viewing.

No mechanical modifications are necessary or will be made to the ECAT PET scanner itself. Other than the integrated 'ECAT SCINTRON PET' workstation, the ECAT PET scanner will consist of the same components as those used in the original CTI PET System including gantry and the patient handling system.

The design and development processes of the 'ECAT SCINTRON PET' integrated workstation are conform to currently valid standards including applicable medical device safety and performance. All modifications do not significantly affect the safety and effectiveness of the device. All test results are, in opinion of MiE GmbH, that the 'ECAT SCINTRON PET' is substantially equivalent to the predicated devices integrated workstation.

## Conclusion

The current device 'ECAT SCINTRON PET' is based on well established technologies and components. It uses the reliable and long term available VME-bus, PowerPC based CPUs and specialized MiE Hard- and Software. Permanent quality control of the delivered components as well as extensive tests of all systems before installation ensures the quality and reliability of the MiE devices.

The 'ECAT SCINTRON PET' integrated workstation has similar intended use, function, operating principle and fundamental technologies as legally market devices with changes in the availability of hardware components and software technologies e.g. graphical user interface. The design and development processes of the 'ECAT SCINTRON PET' are in conformity to currently valid standards including applicable medical device safety and performance.

All test results are, in opinion of MiE GmbH, that the 'ECAT SCINTRON PET' is substantially equivalent to the predicated devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 19, 2013

MiE GmbH
% Mr. Thomas Kuehl
Hauptstrasse 112
23845 Seth, Schleswig-Holstein
GERMANY

Re: K130269
Trade/Device Name: ECAT Scintron PET
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: KPS
Dated: February 6, 2013
Received: February 11, 2013

Dear Mr. Kuehl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division Radiological Health
Office of *In Vitro* Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K130269

Device Name: ECAT Scintron PET

Indications for Use:

The 'ECAT Scintron PET' integrated workstation is designed to acquire data, process and display images, by appropriated trained health care professionals, from ECAT EXACT and ECAT ACCEL PET scanners of CTI PET Systems via measuring the distribution of injected positron emitting radiopharmaceutical in humans for purpose of determining various metabolic and physiologic functions within the human body.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

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